

68-7-10. Pharmacy-based drug distribution systems in ~~adult care homes~~ long-term care facilities; definitions; emergency medication kits. (a) ~~Definitions.~~ Each of the following terms, as used in this regulation, shall have the meaning specified in this subsection:

(1) ~~“Adult care home” has the same meaning as set forth in K.S.A. 39-923.~~ “Automated drug delivery system” means a robotic, mechanical, or computerized device that is used to supply drugs for administration and meets the requirements of K.A.R. 68-9-3.

(2) “Formulary” means a prescription drug list approved by the pharmacy and therapeutics committee or an equivalent committee governing the security, control, and distribution of drugs within a long-term care facility.

(3) “Long-term care facility” means “nursing facility,” as defined in K.S.A. 39-923 and amendments thereto.

(4) “Traditional system” means a drug distribution system in which the pharmacist receives a prescription order for an individual patient and fills the prescription in any manner other than packaging individual doses in unit-dose containers.

(5) “Unit-dose container” means a single-unit or multiple-unit container for articles intended for administration in single doses and directly from the container, by other than parenteral route.

(A) “Multiple-unit container” means a container that permits the withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion.

(B) “Single-unit container” means a container that is designed to hold a quantity of a drug intended for administration as a single dose promptly after the container is opened.

~~(2)(6)~~ “Unit-dose system” means a drug distribution system ~~which~~ that is pharmacy-based and ~~which~~ uses unit-dose containers that enable distribution of packaged doses in a manner that preserves the identity of the drug until the time of administration.

~~(3) "Traditional system" means a drug distribution system in which the pharmacist receives a prescription order for an individual patient and fills the prescription in any manner other than packaging individual doses in unit dose containers.~~

~~(4) "Unit dose container" means a single or multiple unit container for articles intended for administration in single doses, directly from the container, by other than parenteral route.~~

~~(A) "Multiple unit container" means a container that permits withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion.~~

~~(B) "Single unit container" means a container that is designed to hold a quantity of a drug intended for administration as a single dose promptly after the container is opened.~~

(b) All Each pharmacy-based drug distribution systems system for adult care homes a long-term care facility shall meet the following requirements:

(1) Be consistent with the medication needs of the each patient;

(2) conform to all federal and state laws and regulations pertaining to pharmacies; and

(3) ~~conform to~~ meet the following additional requirements:

(A) ~~All prescriptions (unit dose or traditional)~~ Each prescription shall be dispensed from a pharmacy within a ~~reasonable length of time after the medication is ordered.~~ period that reasonably meets the needs of the patient, considering the following factors:

(i) The need for the drug as an emergency;

(ii) the availability of the drug;

(iii) the pharmacy's hours of operation; and

(iv) the stability of the drug;

(B) the supplying pharmacy shall be responsible for the safe delivery of drugs to a designated

person or persons in the ~~adult care home~~, long-term care facility;

(C) the supplying pharmacy shall provide a method of identifying the date and quantity of medication dispensed;

(D) a patient medication profile record system shall be maintained for each ~~adult care home~~ long-term care facility patient serviced by the supplying pharmacy and shall contain the information necessary to allow the pharmacist to monitor each patient's drug therapy; and

(E) ~~All~~ each medication distribution system ~~containers~~ container shall be labeled to permit the identification of the drug therapy.

(c) ~~All~~ Each unit-dose ~~drug distribution systems~~ system shall meet the following requirements, in addition to the ~~above~~ requirements, ~~conform to the following requirements~~ in subsection (b):

(1) All medication shall be packaged in unit-dose containers as far as practicable; and the packaging shall ~~conform to the provisions~~ meet the requirements of K.A.R. 68-7-15 and 68-7-16.

(2) The pharmacist shall be responsible for filling and refilling prescriptions or ~~practitioner's~~ prescriber's orders, or both, according to the directions of the ~~practitioner~~ prescriber by relying on the original prescription or ~~practitioner's~~ prescriber's order or a ~~direct~~ copy thereof.

(3) The pharmacist shall comply with all requirements for prescription orders, including inventory and ~~record keeping~~ recordkeeping requirements, under the following:

(A) The Kansas uniform controlled substances act, K.S.A. 65-4101 et seq. and amendments thereto;

(B) the Kansas pharmacy act, K.S.A. ~~65-1601~~ 65-1625 et seq. and amendments thereto;

(C) the board's applicable regulations in ~~K.A.R. 68-20-1 et seq.~~ and K.A.R. 68-1-1 et seq. articles 1 and 20; and

(D) all federal laws and regulations applicable to prescriptions or medication orders.

(4) Unit-dose dispensing shall take place at the address of the pharmacy providing the unit-dose system.

(5) Container requirements for unit-dose ~~distribution~~ systems may include trays, bins, carts, and locked cabinets if the requirements of K.A.R. 68-7-14 are ~~complied with~~ met. If these options are used, all patient medication trays or drawers shall be sufficiently labeled to identify ~~the~~ each patient.

(6) Each unit-dose ~~distribution~~ system shall provide a verification check at the point of patient administration in order to ~~insure~~ ensure proper drug utilization.

(7) The delivery time-cycle or hours of exchange shall not be limited to a specific time, but shall depend upon the pharmacist's discretion, the needs of the ~~adult care home~~ long-term care facility, the stability of the drug, and the type of container used.

(8) The pharmacist ~~or a pharmacy intern under the direct supervision of a pharmacist~~ shall have sole responsibility for dispensing under the unit-dose system.

(d) ~~Emergency medication kits.~~

(1) Each emergency medication ~~kits~~ kit shall contain only the drugs ~~which~~ that are generally regarded by practitioners as essential to the prompt treatment of sudden and unforeseen changes in a patient's condition ~~which~~ that present an imminent threat to the patient's life or well-being.

(2) ~~Drugs~~ Each drug to be contained within an emergency medication ~~kits~~ kit shall be approved by the ~~adult care home~~ long-term care facility's pharmaceutical services committee (or its equivalent), either of which shall be composed of at least a practitioner and a pharmacist.

(3) The pharmacist providing each emergency medication kit shall ~~conform to~~ ensure that the following requirements are met:

(A) The kit shall be supplied by a pharmacist, who shall retain possession of the drug until it is administered to the patient upon the ~~proper~~ valid order of a ~~practitioner~~ prescriber.

(B) If the kit is not in an automated drug delivery system, the kit shall be locked or sealed in a manner that ~~obviously reveals~~ indicates when the kit has been opened or tampered with.

(C) The kit shall be securely locked in a sufficiently well-constructed cabinet or cart ~~and~~ or in an automated drug delivery system, with drugs properly stored according to the manufacturer's recommendations. Access to the cabinet or cart shall be available only to ~~the~~ each nurse ~~or nurses as determined~~ specified by the pharmaceutical services committee or its equivalent.

(D) The kit shall have an expiration date equivalent to the earliest expiration date of the drugs within the kit, but in no event more than one year after all of the drugs were placed in the kit.

(E) Unless the kit is in an automated drug delivery system, all drugs contained within the emergency medication kit shall be returned to the pharmacy as soon as the kit is has been opened, along with the ~~practitioner's~~ prescriber's drug order for medications administered. (Authorized by ~~and~~ K.S.A. 65-1630; implementing K.S.A. 2015 Supp. 65-1637, K.S.A. 2015 Supp. 65-1642, and K.S.A. 65-1648; effective May 1, 1978; amended May 1, 1983; amended Sept. 9, 1991; amended P-
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